

**REMARKS**

Applicant has added new claim 5 to further describe an embodiment of the invention wherein the Glycyrrhiza glabra and Picrorhiza kurroa are mixed with an excipient, and has added new claims 6-11 directed to a method of treating a patient suffering from liver disease or ailments associated with liver disease.

**35 U.S.C. §112 Rejections**

The Examiner has rejected claims 1-4 under 35. U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner has asserted that claim 1 is rendered vague and indefinite by the term “characterized by” on the basis that it is ambiguous, and urges that it is not clear whether extracts of both Glycyrrhiza glabra and Picrorhiza kurroa are used. Applicant has amended claim 1 such that it no longer recites the phrase “characterized by” and instead recites “consisting essentially of”. Applicant has also amended claim 1 to clarify that the composition contains an extract of Glycyrrhiza glabra and an extract of Picrorhiza kurroa. Accordingly, the basis for the Examiner’s rejection of claim 1 has been overcome. The Examiner is respectfully requested to withdraw the rejection.

The Examiner has rejected claims 2-4 as rendered indefinite by the phrase “characterized in that” and “characterized by”. Applicant has amended claim 2 such that is no longer recites either phrase. Accordingly, the basis for the Examiner’s rejection has been overcome and the Examiner is respectfully requested to withdraw the rejection of claim 2 on this basis.

Applicant has cancelled claims 3 and 4 and thus, the Examiner's rejection of these claims is rendered moot.

**35 U.S.C §102(b) Rejection**

The Examiner has rejected claim 1 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,693,327 ("the '327 patent") to Shah. The Examiner has urged that the patent teaches a composition comprising an extract of *Glycyrrhiza glabra* and an extract of *Picrorhiza kurroa* within the weight ratio range of 2-1:1-3 as claimed. Applicant respectfully traverses this rejection.

To anticipate claim 1, the '327 patent must disclose each and every limitation of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.3d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As amended, claim 1 is directed to a synergistic composition for the treatment of liver and liver associated ailments consisting essentially of an extract of *Glycyrrhiza glabra* and an extract of *Picrorhiza kurroa* in a ratio of from 2-1:1-3 by weight. The claim has been amended to recite the transition phrase "consisting essentially of" which limits the scope of the claim to the specified materials and those that do not materially affect the basic and novel characteristics of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

The Shah patent does not anticipate claim 1 because it fails to teach a synergistic composition for the treatment of liver and liver associated ailments as claimed. Rather, Shah teaches different compositions than presently claimed for the treatment of skin disorders.

Shah teaches a composition that contains an extract from *Melia azadirachta* or an extract from *Centratherum anthelminthicum* or a combination of both extracts and in one embodiment teaches a composition containing one or both of the extracts further comprising extracts derived from at least one member of the group consisting of the plants *Phyllanthus emblica*, *Hemidesmus indicus*, *Tinospora cordifolia*, *Curcuma longa*, *Terminalia chebula*, *Terminalis belerica*, *Berberis aristata*, *Zingiber officinalis*, *Piper longum* *Piper nigrum*, *Rubia cordifolia*, *Smilex china*, *Glycerhiza glabra*, *Picrorhiza curroa*, *Curcuma aromatica* and *Asparagus racemosus*.

There is no teaching in Shah relating to a composition consisting essentially of an extract of *Glycyrrhiza glabra* and an extract of *Picrorhiza kurroa* in the ratio presently claimed for the treatment of liver and liver associated ailments. Thus, the Examiner's rejection of claim 1 under §102(b) over this reference is improper. Applicant respectfully requests the Examiner to withdraw the rejection.

**35 U.S.C. §103 Rejection**

The Examiner has rejected claims 1-4 under 35 U.S.C. §103(a) as being unpatentable over the Shah patent for the reasons set forth in the §102(b) rejection and in addition, on the basis that Shah teaches that the herbal compositions taught therein have numerous therapeutic uses including having anti-inflammatory activity which is one of the disclosed activities of the instant herbal extract composition. The Examiner has urged that Shah further teaches that it is well known in the art to utilize *glycerhiza glabra* in combination with *Picrorhiza curroa* as disclosed at cols 9-10, Herbal #13 . The Examiner has taken the position that applicant's disclosure that the two herbal extracts can be prepared in any known manner indicates that any type of extract from the recited herbals reads upon optimized extracts thereof. The Examiner has also urged that Shah indicates that the various proportions and amounts of the

ingredients used within such herbal composition are result effective variables that would be routinely optimized by one of ordinary skill in the art, and that it is within the purview of the skilled artisan to select and optimize the working conditions. The Examiner has urged that when an applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. §102 and §103. This rejection is respectfully traversed.

The Examiner's rejection under §103 is premised on his assertion that the composition taught in Shah appears to be the same as that presently claimed, and his position that absent a structural difference, the intended use is not limiting. As set forth above, applicant's claim 1 is directed to a synergistic composition for the treatment of liver and liver associated ailments consisting essentially of extract of Glycyrrhiza glabra and an extract of Picrorhiza kurroa in a ratio of from 2-1:1-3 by weight. The Shah patent does not disclose a composition consisting essentially of extracts of Glycyrrhiza glabra and Picrorhiza kurroa as claimed, but rather teaches a composition comprising an extract derived from the plant Melia azadirachta or Centratherum anthelminthicum individually, or in combination and in one embodiment further comprises extracts derived from at least one member from a group of fourteen plants that includes Glycerhiza glabra and Picrorhiza curroa.

Claim 1, as amended, recites the transition phrase "consisting essentially of" which limits the scope of the claim to the specified materials and those that do no materially affect the basic and novel characteristics of the claimed invention. *In re Herz*, 537 F.2d 549, 552-52, 190 USPQ 461, 463 (CCPA 1976). The addition of an extract derived from the plant Melia azadirachta or an extract derived from the plant Centratherum anthelminthicum would materially affect the basic and novel characteristics of the claimed invention. The Examiner's rejection is improper because the composition disclosed in the '327 patent and

that presently claimed by applicant are not the same as asserted by the Examiner.

Accordingly, the composition taught in the '327 patent cannot properly be asserted to inherently have the same use as the composition claimed by applicant, specifically to be useful for the treatment of liver and liver associated ailments as recited in applicant's claim 1. Accordingly, the Examiner's rejection of claim 1 on this basis is in error and should be withdrawn.

Claim 2 depends from claim 1 and thus includes the limitations of claim 1. For the reasons set forth above, the '327 patent does not render obvious claim 2. The Examiner is respectfully requested to withdraw his rejection of claims 1 and 2 on this basis.

### CONCLUSION

In view of the reasons set forth above, Applicant respectfully submits that all pending claims are in condition for allowance. If, for any reason, the Examiner disagrees, he is requested to contact the undersigned attorney at 202-736-8079 in an effort to resolve any matter still outstanding. Favorable reconsideration is respectfully requested.

Respectfully submitted,

  
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